

## REMARKS/ARGUMENTS

A typographical error is corrected in claim 1.

The only outstanding issue is a section 103 rejection over the combination of Hesch, Horrobin, Shibutani, and Riley.

The Office Action alleges that “it would have been obvious ... to add diegonest to the androgen deficiency treatment disclosed by Hesch et al to achieve the beneficial effect of preventing prostate cancer in view of Shibutani et al in light of the fact that androgen deficiency can give rise to prostatic hypertrophy in view of Hesch et al which in turn can lead to prostate cancer in view of Horrobin.” Horrobin is alleged to teach that “those with benign prostatic hypertrophy are at risk of developing prostatic cancer.”

Horrobin, however, does not reflect recent medical thinking on the issue of whether the risk for prostate cancer is elevated for those affected with benign prostatic hypertrophy.

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Applicants attach NIH Publication No. 02-3012 printed from [kidney.niddk.nih.gov/...](http://kidney.niddk.nih.gov/) and bring the attention of the Examiner to page 12 to the heading “BPH and Prostate Cancer: No Apparent Relation” and to text under the heading stating that “having BPH does not seem to increase the chances of getting prostate cancer.” Applicants also attach a document from the American Prostate Society printed from [www.amerirpos.org/bph.html](http://www.amerirpos.org/bph.html) and bring the attention of the Examiner to page 2, first full paragraph, stating that “People sometimes ask if an enlarging prostate increases the risk of prostate cancer. There is no connection.” A further document attached is a printout from MCG Health Systems from their web page [www.mcghealth.org/...](http://www.mcghealth.org/) stating in paragraph 2 on the first page that “having BPH does not seem to increase the chances of getting prostate cancer.” Thus, one of ordinary skill in the art in view of the overwhelming evidence to the contrary would not believe the teaching of Horrobin on the issue of increased risk for prostate cancer for those affected by BPH. It readily follows that the logic used by the Patent Office in the allegation that the claimed invention is obvious is incorrect at least in that BPH does not lead to prostate cancer. The reconsideration of the rejection is respectfully requested for at least this reason.

Additionally, with respect to the other references and the claims, applicants first point out that a patient receiving the composition according to the claims is one affected by testosterone

deficiency. The prophylaxis for the development of benign prostatic hyperplasia or prostate cancer is simultaneously achieved in the same patient.

Hesch teaches that "testosterone-based compounds can be used in particular to treat benign hypertrophy of the prostate and carcinoma of the prostate." See column 7, lines 35-37. Hesch does not teach or suggest that prophylaxis for the development of benign prostatic hyperplasia or prostate cancer can be achieved by the administration of a testosterone or any other compound.

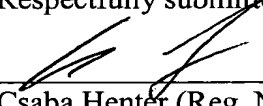
Shibutani does not teach or suggest the administration of a dienogest to a patient who has a testosterone deficiency, i.e., is in need of compensating for an absolute or relative testosterone deficiency, whether such is with or without the simultaneous prophylaxis in said patient for the development a prostate cancer. Shibutani thus does not provide the motivation to one of ordinary skill in the art to practice the claimed method, which requires that the administration be to a patient having testosterone deficiency.

Riley only addresses the dosages of androgens and gestagens independently of each other. Independent claim 1 does not recite dosages, nor is it directed to the independent administration of the components taught in Riley. Thus, Riley does not render any part of claim 1 obvious.

Applicants submit that none of the prior art reference teach or suggest the claimed invention. Thus, the claims are not obvious.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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